COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27/11/2002
C(2002) 4802

NOT FOR PUBLICATION

COMMISSION DECISION

of 27/11/2002

amending Decision C(2001)286 on the marketing authorization for the medicinal product for human use

"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC.

COMMISSION DECISION

of 27/11/2002

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"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase" entered in the Community register of medicinal products under Nos EU/1/00/168/001-003 authorised by Commission Decision C(2001)286 of 23 February 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Boehringer Ingelheim International GmbH submitted an application to change the package leaflet on 10 September 2002 pursuant to Article 61(3) of Directive 2001/83/EC[3].

(3) The proposed changes are not connected with the contents of the summary of characteristics of the medicinal product in question.

(4) The package leaflet as changed continues to comply with Title V of Directive 2001/83/EC

(5) Decision C(2001)286 should therefore be amended accordingly.

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

a) Annex III B is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 27/11/2002

For the Commission
Erkki LIIKANEN
Member of the Commission